

Attorney Docket No.: DEX-0269
Inventors: Salceda et al.
Serial No.: 10/001,887
Filing Date: November 20, 2001
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REMARKS

Claims 1, 2, 4, 5, 7-9, 15 and 18-20 are pending in the instant application. Claims 1, 2, 4, 5, 7-9, 15 and 18-20 have been rejected. Claim 1 has been amended. Claims 15, 18 and 19 has been canceled. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claim 15 under 35 U.S.C. § 112, second paragraph

The rejection of claim 15 under 35 U.S.C. § 112, second paragraph has been maintained. The Examiner suggests that recitation of "means for determining the presence of the nucleic acid molecule of claim 1 is vague and indefinite. While Applicants respectfully disagree with the Examiner regarding clarity of this phrase in light of teachings of the specification, in an earnest effort to advance the prosecution of this case, Applicants have canceled claim 15, thus mooted this rejection.

Withdrawal of this rejection under 35 U.S.C. § 112, second paragraph, is therefore respectfully requested.

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II. Rejection of Claims 1, 2, 4, 5, 7-9, 15 and 18-20 under 35

U.S.C. § 112, first paragraph - Lack of Written Description

Claims 1, 2, 4, 5, 7-9, 15 and 18-20 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner suggests that parts (c), (d) and (f) of claim 1 cover a large genus of related nucleic acids which are not described and were not in Applicants' possession.

Thus, while Applicants respectfully disagree with the Examiner, in an earnest to advance the prosecution of this case, Applicants have amended claim 1 to delete parts (c), (d) and (f) and canceled dependent claims 18 and 19.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, for lack of written description is therefore respectfully requested.

III. Rejection of Claims 1, 2, 4, 5, 7-9, 15 and 18-20 under 35

U.S.C. § 101 and 35 U.S.C. § 112, first paragraph

The rejection of claims 1, 2, 4, 5, 7-9, 15 and 18-20 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, for lack of utility has been maintained.

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Arguments presented by Applicants in the response filed March 1, 2004 were not found persuasive as the Examiner suggests that mention of Figure 20 in said provisional application and its sequence corresponding to instant SEQ ID NO:63, along with mention of general "mRNA subtraction experiments" with respect to "these markers" does not demonstrate a nexus specifically between SEQ ID NO:63/64 and differential expression in breast cancer. The Examiner suggests that it is unclear what "these markers" refers to in the provisional application and has suggested that Applicants more clearly point out the specific nexus established by this application.

Thus, in an earnest effort to advance the prosecution of this case, Applicants respectfully direct the Examiner to page 21, line 9 through page 22, line 35 of U.S. Provisional Patent Application Serial No. 60/249,998 wherein experiments used to identify transcripts unique to breast tissues or messages overexpressed in breast cancer tissues are set forth and in particular page 22, lines 33-35 of U.S. Provisional Patent Application Serial No. 60/249,998 wherein it is specifically stated that the breast cancer specific markers identified by the experiments described at pages 21, line 9 through page 22, line 35 are depicted in the provisional patent application as Figures

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1 through 27, SEQ ID NO: 1 through 27.

As made clear in MPEP 2107.02, where Applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong" even when there may be reason to believe that the assertion is not entirely accurate. Rather, Office personnel must determine if the assertion of utility is believable to a person of ordinary skill in the art based upon the totality of evidence and reasoning provided. An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion.

Applicants have described experiments wherein SEQ ID NO:63 is differentially expressed in breast cancer tissue. Thus, the utility of SEQ ID NO:63 and related SEQ ID NO:64 is based upon a logical analysis of factual data and establishes a credible utility for the instant claimed invention.

Any further maintenance of this rejection, without some showing supported by specific evidence by the Examiner of any flaw in the logic upon which the utility described herein is based, is clearly improper. See MPEP 2107.02 and *In re Gaubert*, 524 F.2d 1222, 1224, 187 USPQ 664, 666 (CCPA 1975).

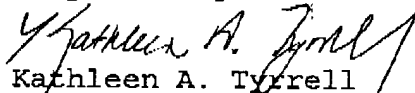
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Withdrawal of this rejection under 35 U.S.C. 101 and 112,
first paragraph is therefore respectfully requested.

IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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